EXHIBIT 6 ABDCMDL00269679



Document 83-7 Filed 11/14/24 Page 2 of 3 U. S. Department of Justice

Drug Enforcement Administration 8701 Morrissette Drive Springfield, Virginia 22152

www.dea.gov

JUN 1 5 2018

Kevin N. Nicholson R.Ph., J.D. Vice President Public Policy and Regulatory Affairs National Association of Chain Drug Stores 1776 Wilson Boulevard, Suite 200 Arlington, Virginia 22209

Dear Mr. Nicholson:

This is in response to your letter dated February 7, 2018, to the Drug Enforcement Administration (DEA) requesting that the DEA address several questions relating to various systems that are utilized by distributors to detect controlled substance suspicious orders. The two systems referenced in your letter are statistically driven threshold incursion systems and "Order of Interest" systems. The DEA appreciates the opportunity to address your request.

The Controlled Substances Act (CSA) and its implementing regulations have established a closed system of distribution so that a controlled substance is at all times under the legal authority of an entity registered with the DEA, or specifically exempted from registration, until the substance reaches the ultimate user (e.g., patient), or is destroyed. This closed system helps the DEA detect and prevent diversion of controlled substances by controlling and monitoring the movement of these substances along the supply chain.

Under federal law, all manufacturers and distributors are required to maintain effective controls against diversion. 21 United States Code (U.S.C.) § 823. DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Specifically, 21 C.F.R. § 1301.74(b) states, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances." This regulation clearly places the responsibility on the registrant to design and operate such a system. Accordingly, the DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.

On February 14, 2018, in an effort to assist controlled substance manufacturers and distributors with their regulatory obligations, the DEA launched a new feature to its ARCOS Online Reporting System. This newly added function allows more than 1,500 DEA registered manufacturers and distributors to view the number of competitors who have sold a particular controlled substance to a prospective customer in the preceding six months. This new tool will provide valuable information for distributors to consider as part of their required assessment.

Finally, the DEA has proposed to revise its regulations relating to suspicious orders of controlled substances. The proposed rule defines the term suspicious order and specifies the procedures a registrant must follow upon receiving such orders. You can monitor the progress of the Suspicious Orders of Controlled Substances Proposed Rule on the Unified Agenda located at

Kevin N. Nicholson, R.Ph., J.D.

Page 2

www.regulations.gov. The above stated proposed rule has been assigned Regulatory Identification Number (RIN) 1117-AB47.

If approved, the proposed rule will be published in the Federal Register and posted on both the DEA's website and www.regulations.gov. At that time, the public will have 60 days in which to submit written comments in response to the proposed rule. The DEA will carefully consider all timely comments in preparing a Final Rule for publication in the Federal Register.

I trust this letter adequately addresses your inquiry. For information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Liaison and Policy Section at (202) 307-7297.

Sincerely,

James Arnold, Chief

Liaison and Policy Section
Diversion Control Division